Endovascular aneurysm repair in high-risk patients

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Purpose: The purpose of this study was to evaluate the role of endovascular aneurysm repair in high-risk patients.
Methods: The elective endovascular repair of infrarenal aortic aneurysm was performed in 116 high-risk patients with either custom-made or commercial stent grafts. The routine follow-up examination included contrast-enhanced computed tomography (CT) before discharge, at 3, 6, and 12 months, and annually thereafter. Patients with endoleak on the initial CT underwent re-evaluation at 2 weeks. Those patients with positive CT results at 2 weeks underwent endovascular treatment.
Results: Endovascular repair was considered feasible in 67% of the patients. The mean age was 75 years, and the mean aneurysm diameter was 6.3 cm. The American Society of Anesthesiologists grade was II in 3.4%, III in 65.5%, IV in 30.1%, and V in 0.9%. There were no conversions to open repair. Custom-made aortomonoiliac stent grafts were implanted in 77.6% of the cases, custom-made aortoaotic stent grafts in 11.2%, and commercial bifurcated stent grafts in 11.2%. The 30-day rates of mortality, major morbidity, and minor morbidity were 3.4%, 20.7%, and 12%, respectively, in the first 58 patients and 0%, 3.4%, and 3.4%, respectively, in the last 58. The late complications included five cases of stent graft kinking, two cases of femorofemoral graft occlusion, and three cases of proximal stent migration, one of which led to aneurysm rupture. At 2 weeks after repair, endoleak was present in 10.3% of the cases. All the type I (direct perigraft) endoleaks underwent successful endovascular treatment, whereas only one type II (collateral) endoleak responded to treatment. The technical success rate at 2 weeks was 86.2%, and the clinical success rate was 96.6%. The continuing success rate was 87.9%. Seventeen patients died late, unrelated deaths.
Conclusion: Endovascular aneurysm repair is safe and effective in patients at high risk, for whom it may be the preferred method of treatment. (J Vasc Surg 2000;31:122-33.)

High-risk patients tolerate the physiologic stresses of conventional open repair poorly, leading to high mortality and morbidity rates. Endovascular aneurysm repair is an appealing option in these patients because it avoids abdominal operation, retroperitoneal dissection, and aortic clamping, thereby minimizing the cardiac, pulmonary, gastrointestinal, and metabolic effects.[1-5]

We report a prospective evaluation of endovascular aneurysm repair in 116 high-risk patients who were with large infrarenal aortic aneurysms. The first and second halves of the study were compared to examine the effect of increasing experience on perioperative mortality, perioperative morbidity, and continuing success rates.

METHOD

This study was performed with two individual, investigator-sponsor, investigational device exemptions from the Food and Drug Administration, one for our own custom-made device[6,7] and the other for a commercial device (Zenith, Cook, Inc, Bloomington, Ind) that was originally developed by the team in

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Table I. Eligibility criteria

1. One of the following:
   a. Fusiform AAA > 6 cm in diameter.
   b. Fusiform AAA > 5 cm in diameter and enlarging at a rate > 5 mm / year.
   c. Saccular AAA > 5 cm in diameter.
   d. False aneurysm of the aorta.
   e. Symptomatic or inflammatory AAA.
   f. AAA associated with an iliac aneurysm > 35 mm in diameter.
2. High risk.
3. Life expectancy > 2 years.
4. Ability to give informed consent.
5. Willingness to comply with follow-up examination.
6. Absence of allergy to stainless steel, polyester, or contrast material.
7. Absence of serious systemic or groin infection.
8. Absence of coagulopathy, unless anticoagulant induced.

AAA, Abdominal aortic aneurysm.

Table II. Anatomic exclusion criteria for the custom-made stent graft

1. Neck (proximal implantation site) that is:
   a. < 10 mm in length.
   b. > 28 mm in diameter.
   c. thrombus lined.
   d. conical (≥ 4 mm larger at its distal end).
   e. severely angulated (> 80° relative to the aneurysm).
2. Iliac artery diameter < 7 mm bilaterally (after balloon dilatation, if necessary).
3. Common iliac artery diameter > 20 mm, bilaterally.

Fig 1. Maximum intensity projection of preoperative spiral computed tomographic scan that shows conical, angulated proximal implantation site (neck).

Perth, Australia.[8] Both protocols were approved by the university's human studies review board, and both restricted endovascular treatment to patients who were thought to be poor candidates for conventional surgical treatment. In the 3 years since the study began, our approach has changed in several regards. The following methods describe our current practice.

Patient selection. The eligibility criteria are listed in Table I. The designation of "high risk" is made on the basis of a variable assortment of clinical and laboratory criteria. We do not apply a rigorous system of preoperative testing and risk quantification[9-11] because we decided that no patient would be considered too sick to undergo endovascular treatment unless their life expectancy was less than 2 years. Some patients have already undergone measurements of cardiac perfusion and ventricular function when they are seen, and some have not.

The patients who meet the eligibility criteria undergo computed tomographic (CT) and angiographic assessement of arterial anatomy to determine the feasibility of endovascular aneurysm repair. The anatomic exclusion criteria have become slightly less restrictive as the study has progressed. The current criteria for the custom-made device are listed in Table II. Many patients are excluded on the grounds of a single criterion, such as the absence of a nondilated segment of aorta between the renal arteries and the aneurysm (a neck), but we also weigh the combined effects of several different factors. Relative contraindications, such as a conical neck, are more likely to be overlooked if they occur in isolation or if they occur in the presence of pressing indications for endovascular repair. Fig 1 illustrates this point. We have less experience with the Zenith device, and therefore, the anatomic exclusion criteria (Table III) are slightly more restrictive.

Device description. Most of the patients in this series underwent treatment with a custom-made stent graft[6,7] that consisted of two Z stents (Cook, Inc) and a tubular, or tapered, sleeve of conventional graft fabric (Cooley Verisoft, Meadox Medicals, Inc, Oakland, NJ). The proximal stent carries four caudally directed barbs and four hooks. The distal stent is unbarbed. The tapered grafts are produced with the creation of an anastomosis between the

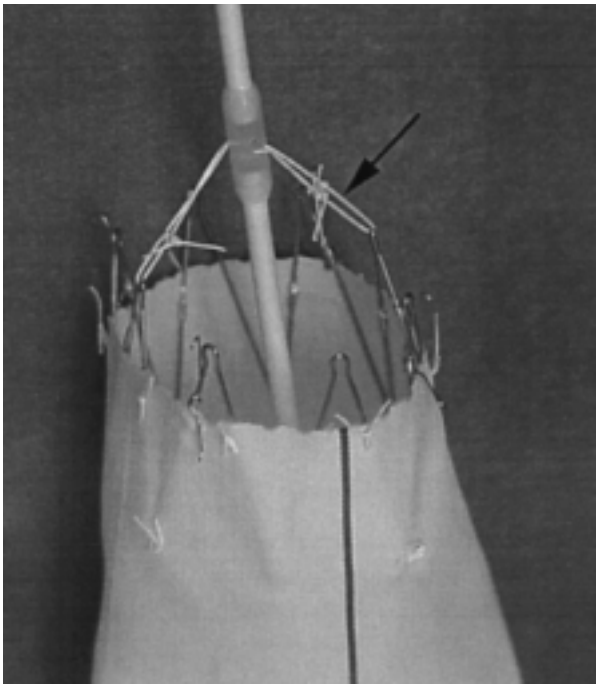

Fig 2. Proximal end of custom-made stent graft that shows suture loops that tether it to delivery system.

Table III. Anatomic exclusion criteria for the Zenith stent graft

1. Neck (proximal implantation site) that is:
   a. < 15 mm in length.
   b. ≥ 28 mm in diameter.
   c. thrombus lined.
   d. conical.
   e. severely angulated (> 60° relative to the aneurysm).
2. Iliac artery diameter < 7.5 mm on either side (after balloon dilatation, if necessary).
3. Severe iliac occlusive disease, tortuosity, or calcification.
4. Iliac artery diameter > 20 mm at the implantation site.
5. Iliac implantation site < 14 mm in length.
6. Indispensable inferior mesenteric artery.

large diameter proximal segment and the smaller distal segment. Each stent graft is sized with reference to the findings of preoperative imaging. The proximal end of the stent graft is tethered by short suture loops to a carrier (Fig 2) and inserted inside an 18F (inner diameter) sheath.

Recently, we have started to use another Z stent–based stent graft, the Zenith system. This is a fully stented, modular, bifurcated stent graft.[8] Its most notable feature is the completely uncovered proximal stent (Fig 3), which is intended for routine suprarenal implantation and carries nine caudally oriented barbs at four different levels to enhance fixation.

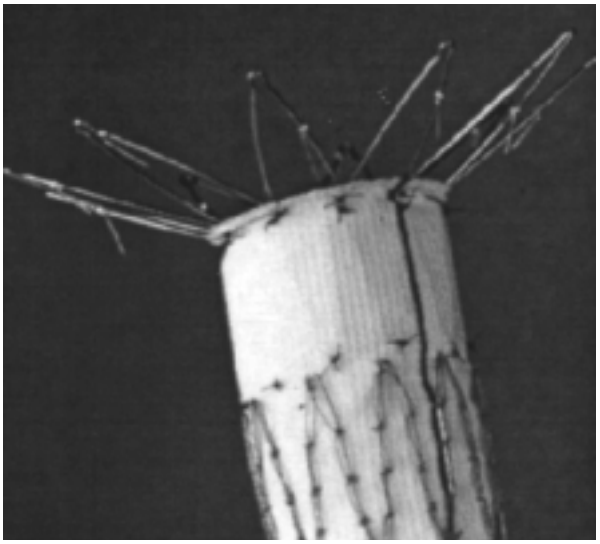

Fig 3. Proximal end of Zenith stent graft that shows uncovered proximal stent and its barbs.

The version of the Zenith system that was used in this study, the TriFab system, is inserted in three parts: a long aortic component and two iliac components. The aortic component has two distal docking sites, one for each iliac component. The docking site opposite the side of aortic component insertion (the contralateral docking site) is 30 mm shorter than the other and carries radioopaque markers to show its axial position within the delivery system.

When the aortic component is loaded into its delivery system, the proximal stent is entirely enclosed within the upstream cap of a carrier, to which it is attached by a trigger wire. The distal stent is attached to the shaft of the carrier by a second trigger wire. A central cannula runs the length of the carrier. Its downstream end is attached to the shaft by a pinch clamp, and its upstream end is bonded to the cap. The trunk of the stent graft and the carrier are both loaded into an 18F (inner diameter) valved sheath. The iliac components are delivered through a smaller (14F), simpler version of the system used for the aortic component. The iliac component delivery system lacks the upstream cap and the trigger wire attachments.

Stem graft sizing. The proximal diameter of the stent graft is oversized by 4 to 6 mm relative to the outer diameter of the neck, as measured on the transaxial CT. The distal stent graft diameter is oversized by 0 to 2 mm relative to the largest diameter of the iliac implantation site, as measured on angiography. The length of the stent graft, or the stent graft

components, is sized with reference to the markings on a calibrated angiographic catheter. The largest diameter that the custom-made delivery system can accommodate is 32 mm.

The Zenith stent grafts are selected from a range of available sizes. The diameter of the aortic component ranges from 20 mm to 32 mm, in 2-mm increments. The length of the aortic component (from the proximal end of the graft fabric to the distal end of the contralateral docking site) ranges from 74 mm to 132 mm, in 14-mm and 15-mm increments. The goal in choosing an aortic segment is to ensure that the contralateral docking site lies as close to the aortic bifurcation as possible, although if any doubt exists regarding the correct length, we tend to err on the side of too short, rather than too long.

The diameter of the iliac components range from 8 mm to 24 mm, in 2-mm increments. The lengths range from 37 mm to 122 mm, in 17-mm increments. The goal in choosing the length of the iliac component is to create at least 30 mm of overlap with the common iliac artery. If there is any doubt regarding the correct length, we tend to err on the side of too long, rather than too short.

Insertion procedure. The basic insertion techniques have been described previously for both our custom-made stent graft[6,7] and the Zenith stent graft,[8] but there have been several minor changes during the course of this study. The current technique is subsequently described.

We expose the femoral arteries bilaterally through oblique incisions at the level of the inguinal ligaments.[12] This approach reflects the results of our early experience,[6] in which standard longitudinal incisions were associated with a high rate of wound complications. Only a short segment of the proximal femoral artery is exposed, even in the cases that require femorofemoral bypass grafting. The deep and superficial arteries are rarely exposed and are never clamped. In the Zenith cases, femoral artery exposure is obtained only as a means of performing femoral artery repair at the end of the operation. The entire procedure is performed through valved sheaths, which obviate the need for arterial occlusion. These sheaths traverse the skin through small stab wounds distal to the primary incisions and enter the softest available areas in the exposed portions of the femoral arteries.

The patients who have unilateral common iliac aneurysms undergo treatment with preoperative internal iliac embolization. We use large coils to occlude the proximal trunks of the internal iliac artery and leave the smaller branches patent to act as potential routes of collateral flow, which thereby minimizes the risk of buttock claudication.

We do not use a brachial-femoral guidewire. If the iliac arteries are tortuous and calcified, the delivery system is inserted over a stiff guidewire (Lunderquist, Cook, Inc). We have never encountered a case in which the delivery system insertion was prevented by iliac tortuosity, and we have encountered only one instance in which the access to the common iliac artery could only be obtained with direct surgical exposure.[13] In that case, the impediment to the delivery system insertion was diffuse iliac stenosis, not tortuosity.

The angiographic catheter enters the arterial tree through the femoral artery on the side opposite the side of stent graft insertion. Unless we encounter problems in aortic catheterization, the first intraoperative angiograms are performed with the stent graft delivery system already inside the aorta. The contrast material is 350 mg/mL iohexol (Omnipaque, Nycomed, Princeton, NJ). The intraoperative type I endoleaks (around the end of the stent graft)[14] are treated with a variety of adjunctive endovascular techniques.[15] The type II endoleaks (through lumbar or inferior mesenteric arteries) are ignored.

Suprarenal stent implantation is a routine part of the Zenith system, which has an entire uncovered stent at its proximal end (Fig 3). Our custom-made stent graft also permits an uncovered portion of the proximal stent to be implanted over the renal artery orifices, which we do in almost every case, unless the neck is long and healthy or the aorta has a sharp bend at the level of renal arteries.

The entire distal segment of the custom-made stent graft is reinforced with Wallstent. In constrast, the Zenith stent graft is supported throughout its length with a series of external Z stents and requires additional support only when the common iliac artery is tortuous. We have seen only one such case (Fig 4), in which the implantation of a Wallstent helped to eliminate a kink in the iliac component of a Zenith stent graft.

Follow-up examination. Aneurysm exclusion was assessed using serial contrast-enhanced CT before discharge, at 3, 6, and 12 months, and annually thereafter. The patients with endoleak on the first postoperative CT results underwent another scan 2 weeks later. If an endoleak was present, the patient underwent angiography and endovascular treatment. The type I (direct perigraft) endoleaks were treated with additional stent grafts.[15] The type II (indirect collateral) endoleaks were treated, whenever possible, with coil embolization of collateral pathways.[15-17]

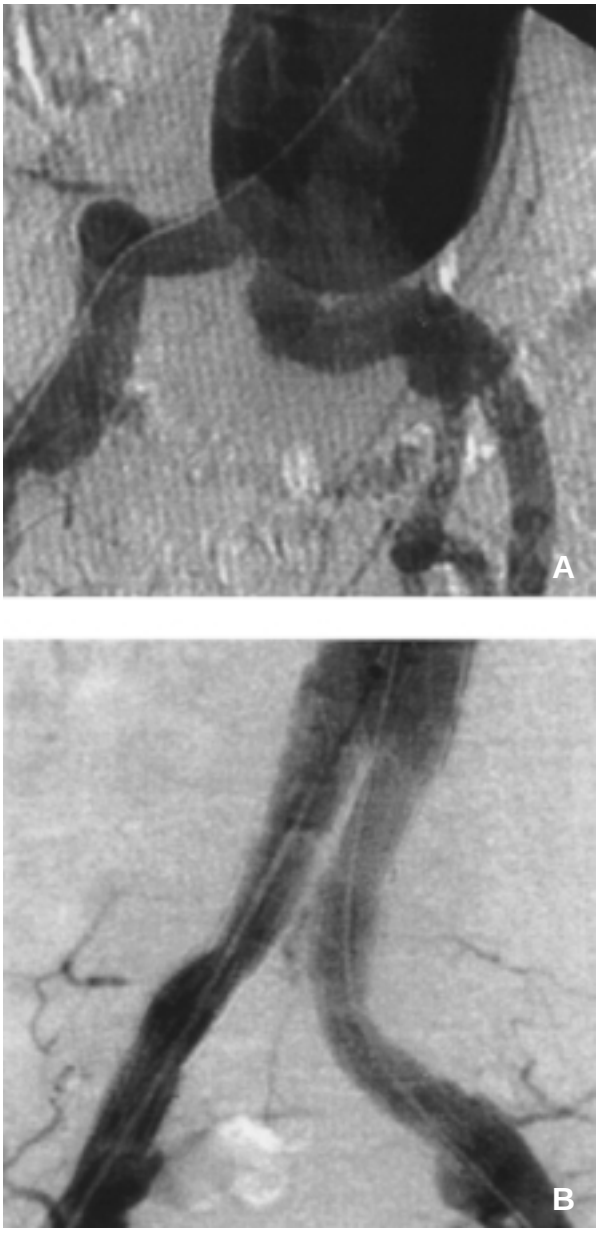

Fig 4. A, Preoperative angiogram that shows angulation of left common iliac artery. B, Completion angiogram that shows smooth curve of left limb of graft, which contains Wallstent.

RESULTS

Endovascular repair was considered feasible in 67% of all the patients who were eligible for inclusion in the study. Most of the patients (93%) who were excluded on anatomic grounds lacked a suitable implantation site between the renal arteries and the aneurysm. Between June 1996 and June 1999, elective endovascular aneurysm repair of abdominal aortic aneurysm (AAA) was performed in 116 patients, with a mean age 75 years and a mean AAA diameter of 6.3 cm. If the aneurysms that were expanding, inflammatory, symptomatic, anastomotic, saccular, or associated with large iliac aneurysms (total, n = 26) are excluded, the mean AAA diameter was 6.6 cm. The American Society of Anesthesiologists (ASA) grade was II in 3.4% of cases, III in 65.5%, and IV in 31%. The comorbidities are listed in Table IV.

Table IV. Comorbidity in 116 patients who underwent endovascular repair

Comorbid conditions	*No. of patients*
Coronary insufficiency	94
Chronic obstructive pulmonary disease	57
Congestive heart failure	39
Renal insufficiency*	25
Obesity	35

*Creatinine level, ≥1.5 mmol / dL.

The procedure was performed with regional (epidural or spinal) anesthesia in 84 cases (72.4%), general in 29 cases (25%), and local in three cases (2.6%). We used custom-made tapered aortomonoiliac stent grafts in 90 cases (77.6%), custom-made straight aortoaortic stent grafts in 13 cases (11.2%), and Zenith bifurcated aortobiiliac stent grafts in 13 cases (11.2%; Fig 5). Stent graft implantation was successful in all 116 cases. None of the cases were converted to open repair. The 116 patients who underwent treatment included many examples of severe arterial distortion, such as neck angulation of more than 60° (21.6%), neck length of less than 15 mm (24%), iliac angulation of more than 90° (19.8% of patients), and iliac aneurysm (13.8% of patients).

The mean operating time (± the standard deviation) was 191 ± 65 minutes, the mean contrast volume was 154.5 ± 84.9 mL, and the mean blood loss was 280.9 ± 374.7 mL. The mean time from operation to resumption of a regular diet was 0.72 ± 0.53 days, to ambulation was 1.08 ± 0.58 days, and to discharge from the hospital was 4.04 ± 2.10 days.

Two patients (1.7%) died within 30 days of the operation: one during attempted ablation therapy for a longstanding arrhythmia and the other of pneumonia after re-exploration of the groin wound for infected lymph fistula. One other patient died after re-exploration of the groin wound for infected lymph fistula. This death occurred 3 months after the original operation.

To illustrate the effects of evolving technique, we have listed the perioperative complications in

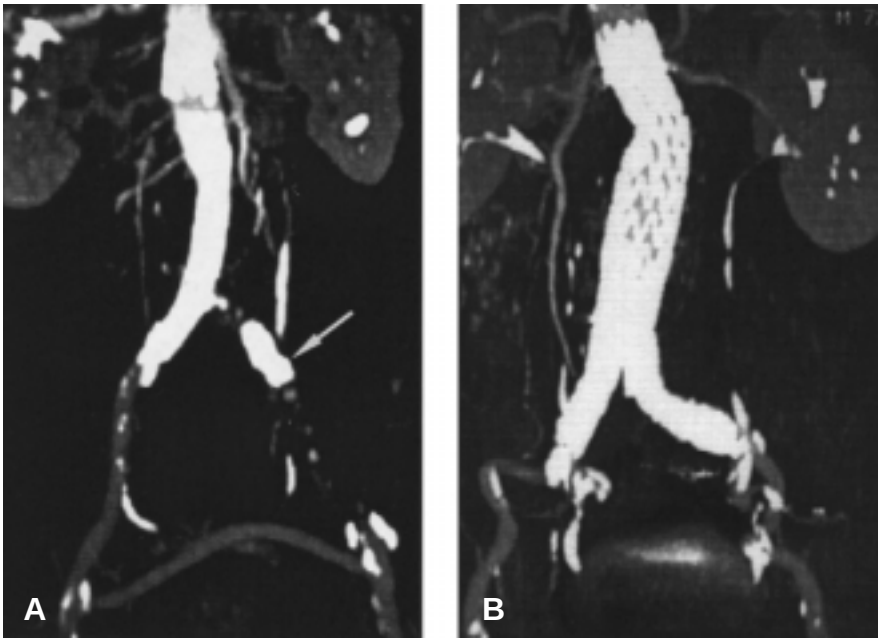

Fig 5. A, Maximum intensity projection of spiral computed tomographic scan that shows tapered aortomonoiliac stent graft, femorofemoral graft, and left common iliac occluder *(arrow)*. B, Maximum intensity projection of spiral computed tomographic scan that shows bifurcated aortobiiliac stent graft.

the following two groups: those that occurred in the first half of the study and those that occurred in the second half (Table V). The most striking difference between the two groups is in the incidence of serious wound complications. All the patients in the latter half of the study underwent treatment with an oblique incision for femoral exposure.[12] The only two wound complications in this group were small areas of necrosis where deep intertriginous folds could not be altogether avoided. The declining number of complications is apparent in the rates of perioperative (30-day) morbidity and mortality (Table VI). In this context, major perioperative morbidity was defined as a complication that delayed discharge more than 5 days or that required readmission within 30 days of operation. The cases of uncomplicated endoleak were not included. In the second half of the study (n = 58), there were no perioperative deaths and a major morbidity rate of 3.4%. Surprisingly, the length of stay did not follow the same trend and rose from 3.5 days in the first half of the study to 4.5 days in the second half.

The mean follow-up period was 15.9 ± 10.23 months (range, 0 to 34 months). The late complications are listed in Table VII. Kinking developed in five cases. All of these cases were treated with additional Wallstents. In four of the five, the lumen was further narrowed by mural thrombus at the kink (Fig 6). All four patients have since undergone anticoagulation therapy with warfarin sodium. Two of these patients had malignant carcinomas. There have been no cases of complete stent graft occlusion. Femorofemoral bypass graft occlusion has occurred

Table V. Perioperative (30-day) complications in the first and second halves of the study

Complications	*First 58 patients*	*Last 58 patients*
Wound infection	5	0
Wound necrosis	4	2
Lymph fistula	2	0
Infected lymph fistula	2	0
Lymphocele	4	1
Re-exploration for hematoma	3	0
Myocardial infarction	4	0
Stroke	0	1
Renal impairment*	1	0
Renal embolism†	0	1
Digital embolism	1	0
Deep venous thrombosis	0	1

*Rise in creatinine level, >1.0 mmol/dL.
†Computed tomographic finding only.

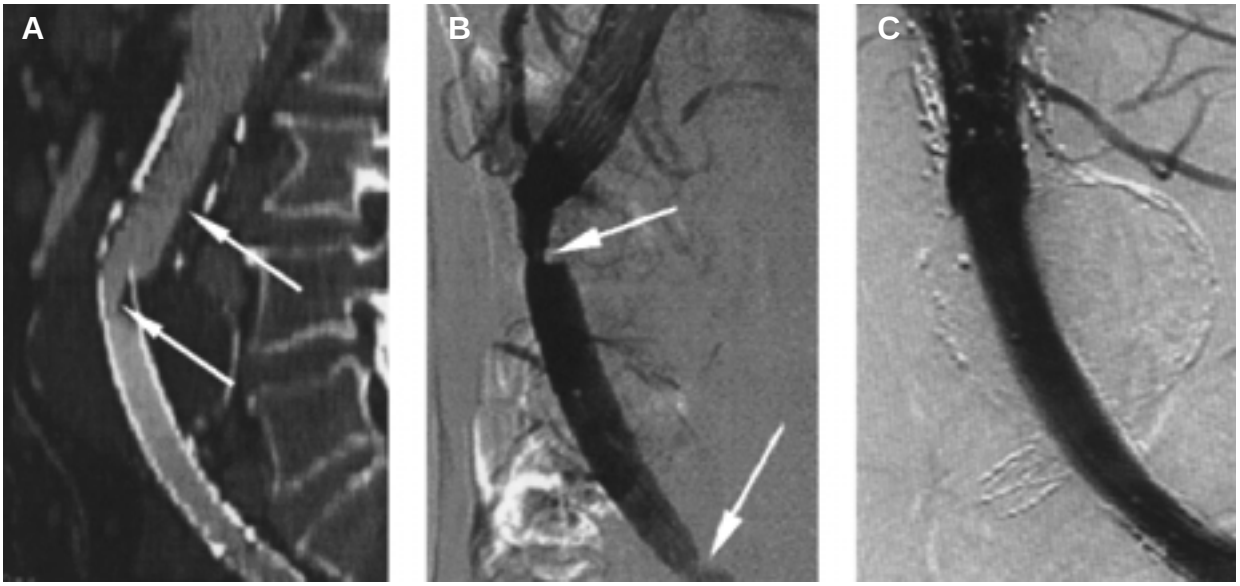

Fig 6. A, Multiplanar reconstruction of spiral computed tomographic scan that shows thrombus lining the stent graft *(arrows)*. B, Angiogram that shows two areas of stenosis *(arrows)*. C, Angiogram after implantation of additional Wallstent and balloon dilatation.

Table VI. Perioperative (30-day) mortality and morbidity rates for the first and second halves of the study

	First 58 patients	*Last 58 patients*
Minor morbidity	7 (12.0%)	2 (3.4%)
Major morbidity*	12 (20.7%)	2 (3.4%)†
Mortality	2 (3.4 %)	0 (0%)

*Discharge delayed by more than 5 days.
†Significant difference between the two groups (P = .01).

twice: once as a result of a tumor-induced hypercoagulable state and once as a result of femoral-popliteal bypass graft occlusion. In the first case, thrombus was extracted with a Fogarty balloon through an access point in the mid graft. In the second case, thrombus within the femorofemoral graft was lysed with urokinase.

There were three cases of proximal stent migration, all of which were treated with additional stent grafts. Two cases were attributed to low implantation at the original operation, followed by dilatation of the implantation site and migration of the undersized stent graft. The other case was attributed to inadequate attachment of the proximal stent to the walls of a short, angulated neck (Fig 7). In two cases, migration was an incidental finding on follow-up imaging. In the other case, proximal stent migration produced secondary endoleak, aneurysm expansion, and rupture. Interestingly, this patient's condition was never hemodynamically unstable. The patient went home 3 days after the implantation of an additional stent graft. At the last follow-up examination, a year after the second operation, the stent graft position had not changed and the aneurysm had shrunk by 25 mm.

Only one late problem was not successfully treated by endovascular means. This man had no signs of endoleak on the first CT results but was lost to follow-up examination almost immediately after discharge from the hospital. No other scans were performed until the patient was seen at a hospital in a different state with abdominal pain. Noncontrast CT showed aneurysm enlargement, which prompted conventional surgical repair. At operation, the only identifiable source of endoleak was a patent lumbar artery.

At 2 weeks after the repair, 12 patients (10.3%) had endoleaks based on CT results. On the basis of subsequent angiography, three of these were type I (around the end of the stent graft), seven were type II (through collaterals), and two were both type I and type II. There were no leaks of types III or IV (through small or large holes in the graft). All the type II leaks resolved after endovascular treatment with additional stents, stent grafts, and embolization coils. Only one of the nine type II leaks resolved, despite

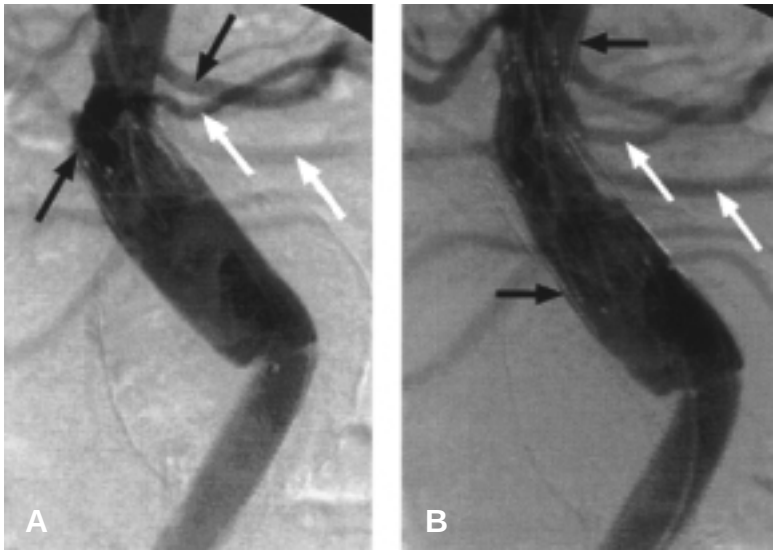

Fig 7. A, Operative angiogram that shows left renal artery *(black arrow)*, top of original stent graft *(black arrow)*, and branches of superior mesenteric artery *(white arrows)*. This stent graft had migrated 5 mm from its original implantation level. B, Completion angiogram after placement of additional stent graft. Proximal and distal stents of stent graft are indicated with *black arrows*. Branches of superior mesenteric artery are indicated with *white arrows*.

the embolization of collateral arteries in five patients. Aneurysm expansion by more than 5 mm occurred in two of the eight patients with persistent type II leaks. Interestingly, aneurysm growth ceased after the coil embolization of collaterals in both patients, despite persistent endoleak on CT. One patient had a secondary type II endoleak develop when he underwent anticoagulation therapy with warfarin sodium a year after operation, which brought the total number of unresolved type II endoleaks back up to nine.

The technical success rate at 2 weeks was 87.1%, and the clinical success rate was 97.4%, as defined by the reporting standards of the Society for Vascular Surgery and the International Society for Cardiovascular Surgery, North American Chapter.[18] At the time of this writing, the continuing success rate (including secondary success) was 87.9%. But this assessment included seven cases of type II endoleak, in which the aneurysm size did not increase, and one case of stent graft explantation for tuberculous aortitis, which spread from the spine. If these cases were excluded, the continuing success rate would be 94.8%.

The survival curve after endovascular aneurysm repair is shown in Fig 8. Of the original 116 patients, 95 are still alive. In addition to the two perioperative deaths and the one late related death, there have been 18 late unrelated deaths. The most common causes of death were myocardial infarction (n = 5) and cerebrovascular accident (n = 6).

Renal infarcts were seen on postoperative CT in four patients. The causes were deliberate occlusion of an accessory renal artery (n = 2), deliberate occlusion of the renal artery to one of two normally functioning kidneys (n = l), and renal atheroembolism from a pararenal aortic plaque (n = l). No new infarcts have been seen on follow-up CT results.

DICUSSION

On the basis of these results, endovascular stent graft implantation appears to be both safe and effective in the group of patients studied. Broader conclusions regarding the role of endovascular aneurysm repair in the management of high-risk patients depend on the answers to two related questions. First, were these truly high-risk patients? Second, is it worthwhile to operate on such patients, given their limited life expectancy?

Although all of these patients had serious comorbidities (Table IV), we lack the data to quantify the risk.[9-11] Our routine preoperative evaluation did not include the testing of cardiac perfusion or ventricular function, and we found that the simplest clinical algorithms did not take account of several factors

Table VII. Late complications of endovascular aneurysm repair in 116 patients

Complications	*No. of patients*
Proximal stent migration	3
Kinking	5
Stent graft occlusion	0
Femorofemoral graft occlusion	2

that would have contributed to the risk of open repair in many of our patients, such as obesity, hostile abdomen, and prior attempts at open repair.

Approximately one third of our patients had an American Society of Anesthesiologists grade of IV, which is more than one would expect in a conventional surgical series but comparable with other studies of endovascular aneurysm repair.[19,20] Nevertheless, we think it unlikely that conventional repair would have produced a 30-day mortality rate of 1.7% in this group of patients. Because we applied no upper limit on the severity of anesthetic risk, some of these patients were very sick. Examples include: two patients with aortic valve gradients greater than 60 mm Hg, two with ventricular ejection fractions less than 20%, and one who had been rejected for cardiac transplantation because of too many comorbidities. A few outliers, such as these, can have a disproportionate influence on an otherwise low mortality rate.[21]

Several other data illustrate the high prevalence of serious cardiac and pulmonary disease among our patients. One example is the projected mortality rate of 25% at 2 years, which we attribute to the ongoing effects of the comorbid conditions rather than the delayed effects of the operation. This rate is higher than the projected late mortality rate of endovascular AAA repair reported by May et al.[20] The difference probably reflects a higher prevalence of severe cardiac and pulmonary disease in our series. Another indirect indicator of high risk among the larger group of patients considered for endovascular repair is the fate of those patients who were refused the operation on anatomic grounds but were otherwise eligible. Despite a mean aneurysm diameter of more than 6 cm, less than half of these patients subsequently underwent open repair, and the perioperative mortality rate was 17%.

The benefits of aneurysm repair depend on the operative mortality, the risk of aneurysm rupture, and the life expectancy.[22] Although the endovascular technique has reduced the risk of operation in high-risk patients, limited life expectancy probably undermines its value. On the basis of the high rate of late mortality observed in this study, we believe that aneurysm repair is hard to justify in high-risk patients unless the risk of rupture is high. Consequently, we do not treat small aneurysms in high-risk patients unless they are expanding, inflammatory, symptomatic, anastomotic, saccular, or associated with large iliac aneurysms.

The difference in complication rates between the first and second halves of the series shows the effect of changes in operative technique, the most important of which relate to femoral artery exposure.[12] Most of the complications that were experienced in the first half of the series were wound problems. These were not minor. The only two deaths truly attributable to the procedure both followed re-exploration for infected lymph fistula. It appears that our patients were prone to the development of wound infection, necrosis, and lymph fistula. One apparent risk factor was a high prevalence of obesity (31%). Nevertheless, these wound problems were avoidable, as the latter half of the series showed. We believe that the improved results in the latter half of the series reflect the beneficial effects of increasing experience and not the effect of chance. Other authors have observed a similar phenomenon.[19,23] The results in the latter half of our series suggest that endovascular aneurysm repair can be accomplished with a major morbidity rate of 3.4% and a mortality rate of 0%.

We were surprised to find that a falling complication rate was not associated with a reduced hospital stay. Although the major morbidity rate fell from 20.7% to 3.4%, the postoperative stay increased from 3.5 days to 4.5 days. The explanation probably lies in our widening referral base and practical constraints on discharging patients who are old and debilitated and who live far away.

Given the high prevalence of preoperative renal impairment (22.4%) and the volume of contrast (154.5 mL), it is perhaps surprising that we observed an increase in the creatinine level of more than 1 mg / dL in only one patient. Other centers have reported higher rates of renal failure after the endovascular repair of AAA.[24] The lack of delayed renal impairment or infarction is also interesting because most of the patients in our study had one or both renal arteries covered by portions of the proximal stent. We did not originally take this approach. When the study began, our policy was to place the proximal stent below the renal arteries, unless the neck was less than 15 mm in length or there were other reasons to believe that the infrarenal aorta lacked a secure implantation site. Our reluctance to implant above the renal arteries slowly declined as it became apparent that this maneuver produced no significant short-term effects on renal func-

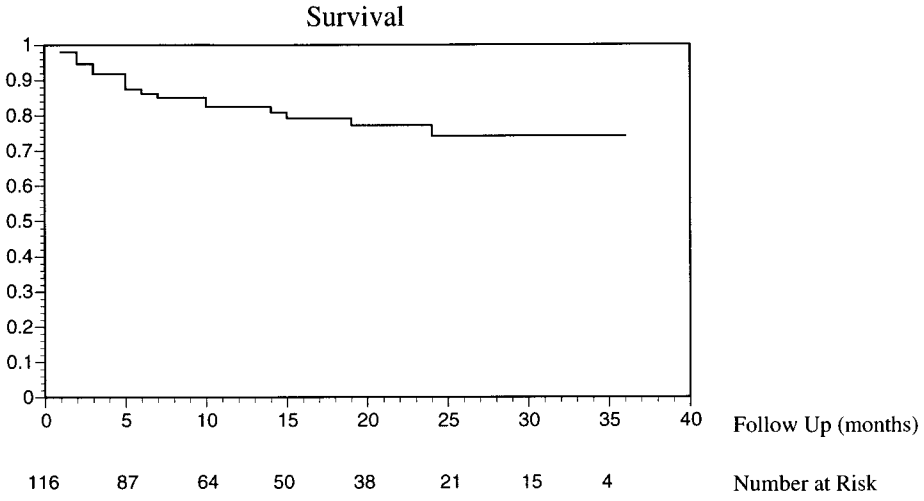

Fig 8. Kaplan-Meier method curve for survival.

tion, whereas proximal stent migration could lead rapidly to graft occlusion, endoleak, and aneurysm rupture. All three instances of proximal stent migration in this series were the result of infrarenal proximal stent implantation.

The operative time, hospital stay, morbidity rate, mortality rate, and success rate all compare well with the results of other large studies of endovascular aneurysm repair.[19-21] Specific concerns relating to the use of an aortomonoiliac stent graft have not been borne out. The main weakness of the aortomonoiliac approach is its reliance on a femorofemoral bypass graft. It appears that femorofemoral bypass grafting has a higher patency rate in patients with aneurysm than in patients with aortoiliac occlusive disease.[25] Other investigators have reported similar findings. We have yet to see a case of stent graft occlusion, probably because significant graft stenosis produced symptoms that allowed its detection and endovascular treatment (Fig 6). The limitations on flow rate imposed by uniiliac outflow do not seem to be a major problem in the patients at high risk, whose activity is more often restricted by general debility or cardiopulmonary disease.

The rate of endoleak at 2 weeks is comparable with the rates in other reported series.[19,21,23] We decided to attempt endovascular treatment in all the cases of endoleak because most of our patients had large aneurysms and aneurysm rupture is a well described consequence of endoleak.[26,27] Endoleak resolution was seen in all of the type I endoleaks but in only one of the type II endoleaks. Nevertheless, embolization of collaterals does seem to have prevented aneurysm expansion in these cases. Persistent type II endoleaks represented the largest cause of failed repair in this series, yet it is still not clear that type II endoleaks represent a significant risk of rupture. Recent reports suggest that aneurysm pulsatility[28] and expansion[29,30] are less for type II endoleaks than for type I endoleaks. Perhaps endoleak, particularly type II endoleak, should not be considered a clear indicator of failed repair unless the aneurysm enlarges or ruptures, and hence, our use of a continuing success rate (95%) that excluded those cases of type II endoleak without increased aneurysm diameter.

Several studies have reported high short-term and medium-term success rates for endovascular repair.[8,19,21,23] This study is no exception. Although the long-term durability of the approach remains to be proven, we believe endovascular repair is the preferred option for high-risk patients at with large aneurysms.

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DISCUSSION

Dr Takao Ohki (Bronx, NY). I would like to thank the organization and Dr Whittemore for giving me the opportunity to discuss this important paper.

Dr Chuter and colleagues have reviewed 116 cases of endovascular repair of abdominal aortic aneurysms, all of which were deemed to be high risk for standard operative repair. The perioperative mortality rate was 3.4% for the initial experience and an impressive 0% for the more recent cases. Endoleak was present in 10% of the cases at 2 weeks. Eighteen patients died unrelated deaths during the mean follow-up period of only 16 months. On the basis of this observation, Dr Chuter concludes that endovascular repair is safe and effective in patients at high risk and, therefore, should be considered the first-line treatment option for these patients.

I have several questions for Dr Chuter. We at Montefiore also have treated patients with abdominal aortic aneurysms who are at high risk for standard repair with a stent graft. The common dilemma that we and others face is whether

there is any validity in repairing an asymptomatic aneurysm if the patient is at high risk for comorbid reasons, and if so, at what size? A paper written by Dr Jones and his colleagues in the *British Journal of Surgery* (1998;85:1382-4) reported the analysis of the natural history of patients at high risk with abdominal aortic aneurysms larger than 5 cm in diameter. In this study, they found that 88% of the patients had died at the end of the study and that the median survival rate was only 18 months. More importantly, only 35% of these deaths were due to aneurysm rupture. On the basis of this observation, Dr Jones has concluded that elective aneurysm repair in this group of patients is not justified because the vast majority of the patients die of other causes. Can you give us your thoughts regarding this dilemma?

One way to answer this question is to analyze what happened to the 77 patients who were excluded from your endovascular protocol on the basis of anatomic grounds. How many of these patients were treated nonoperatively? And what was the mean survival rate for the nontreated patients? In your study, the endovascular group, 18% of the patients treated endovascularly died during the mean follow-up period of only 16 months. Was this number any better than that of the nonoperated group?

You concluded that endovascular repair is safe and effective in patients at high risk. I agree with the first part of your conclusion. However, I have some reservation to say that it is effective. To say it is effective, one must show that the endovascular repair prolonged the patient's life longevity.

You mentioned in your manuscript that the patients were at high risk. However, at the same time, one of your inclusion criteria for both device protocols was that the life expectancy for the patient had to be longer than 2 years. In addition, the American Society of Anesthesiologists (ASA) score was equal to or lower than III in 70% of the patients. I have some difficulties in understanding your definition of high risk. If their life expectancy was longer than 2 years and if the ASA score was equal to or lower than III in the majority of the cases, were they truly high-risk cases? Of those 77 patients who were excluded from the endovascular protocol, how many were treated surgically? And what was the surgical mortality rate of this group of patients? Did they truly represent a high-risk group of patients? Eighteen patients, that is, 16% of the patients at risk, died during the mean follow-up period of 18 months, despite the fact that you only included those patients who were thought to have a life expectancy of 24 months or longer. You mentioned that none of these deaths were related to aneurysm rupture. Making the precise diagnosis without obtaining autopsy may be difficult. In what percent of these unrelated deaths were you able to obtain autopsy? And if autopsy was not obtained, how can you be sure that it was not aneurysm related?

Thank you very much.

Dr Timothy A.M. Chuter. Dr Ohki raises some important points. I think he is right to question whether endovascular repair or any kind of repair is justified in patients at high risk, given their poor long-term survival rates. Obviously, a patient has to live long enough to appreciate the benefits of freedom from risk of rupture.

We tried to make the risk/benefit ratio favor endovascular aneurysm repair in a number of ways. First, we tried to select patients who were going to live more than 2 years. Second, we tried to treat only aneurysms that we believed had a high risk of rupture, which included large fusiform aneurysms, saccular aneurysms, perianastomotic aneurysms, or aneurysms associated with large iliac aneurysms. Third, we tried to keep the operative mortality low. Having achieved those objectives, I think that operation probably was justified.

Regarding the survival of the nonoperated group, I am afraid I just do not have these data.

I would argue that an effective endovascular repair is one that prevents death from aneurysm rupture and avoids open aneurysm repair. By that criterion, we were successful in all of the cases but one. That particular patient deprived us of the opportunity to identify and treat the cause of aneurysm dilatation by declining follow-up examination.

Whether these patients are really at high risk is questioned by Dr Ohki on the basis of the large number who had an ASA class of III and of the exclusion of the patients with a life expectancy of less than 2 years. Well, ASA III is a pretty broad category. Other investigators have shown that among ASA III patients are many on whom you would not want to operate. So, I do not think that is necessarily a reason to think that these were not patients at high risk. And, in fact, if you look at the survival rate of these treated patients, I think you see fairly good reasons to think that they were high risk, although perhaps not so sick as the patients followed by Jones and colleagues in the series you quote. The number of deaths in that series from comorbid conditions was very high, but so was the number of deaths from aneurysm rupture. I certainly think that endovascular repair is justified if the alternative is a 35% mortality rate from aneurysm rupture in only 18 months.

Dr David C. Brewster (Boston, Mass). Congratulations on your report. Certainly we share one of your conclusions, which I believe is that this methodology is best applied to the older patient at higher risk.

I would like your comments, though, on the potential trap of trying to push the envelope, so to speak, in your zeal to use an endovascular method of treatment in the higher risk patient category. I think that in taking on adverse and challenging anatomy, we do increase the hazard of getting into technical trouble and therefore having to convert, in which case the risk is extremely high. Can we have your thoughts on this potential paradox?

Dr Chuter. I agree with you absolutely. An important factor in the risk/benefit analysis is a low mortality rate after repair. And if you have to convert high-risk patients to open surgery, you are not going to have a lot of deaths. So, patients who have high-risk anatomy, that is, short implantation sites, difficult access, etc, together with high-risk physiology, should probably be excluded.